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14. ABSTRACT

Over the course of the last year, all instruments have been completed, programmed, and tested on the study website. The RTI team has hired and trained site coordinators at all six participating installations. In addition, the study team received IRB approval and began recruiting participants at five of the six study sites (Joint Base Lewis-McChord, Ft. Bliss, Ft. Campbell, Ft. Carson, and Ft. Stewart). As of August 31, 2012, 368 total referrals across the five active sites had been received; 179 participants had been enrolled and randomized into the study (86 participants into the STEPS UP arm; 93 participants into the optimized usual care arm); 53 participants completed the 3-month follow-up assessment; and 6 participants completed the 6-month follow-up. We are awaiting HRPO approval of our final site (Ft. Bragg); we anticipate beginning recruitment at Ft. Bragg in September 2012. Multiple amendments have been approved by the RTI IRB, including an amendment that revised eligibility criteria and updated data collection forms.

15. SUBJECT TERMS

PTSD; depression; preference-based stepped care; recruitment, enrollment/randomization, and follow-up; intervention refinement; hiring; training; IRB compliance

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INTRODUCTION:

The purpose of the STEPS UP (**ST**epped **E**nhancement of **P**TSD **S**ervices **U**sing **P**rimary Care) trial is to compare centralized telephonic care management with preference-based stepped PTSD and depression care to optimized usual care. We hypothesize that the STEPS UP intervention will lead to improvements in (1) PTSD and depression symptom severity (primary hypothesis); (2) anxiety and somatic symptom severity, alcohol use, mental health functioning, work functioning; and (3) costs and cost-effectiveness. We further hypothesize that qualitative data will show that (4) patients, their family members, and participating clinicians find that the STEPS UP intervention is an acceptable, effective, and satisfying approach to deliver and receive PTSD and depression care.

STEPS UP is a six-site, two–parallel arm (N = 1,500) randomized controlled effectiveness trial with quarterly follow-up for 12 months comparing centralized telephonic stepped-care management to optimized usual PTSD and depression care. In addition to the existing PTSD and depression treatment options, STEPS UP will include web-based cognitive behavioral self-management, telephone cognitive-behavioral therapy, continuous RN nurse care management, and computer-automated care management support. Both arms can refer patients for mental health specialty care as needed, preferred, and available. The study will use sites currently running RESPECT-Mil, the Initiating PI's existing military primary care–mental health services practice network, to access site health care leaders and potential study participants at the six study sites.

If effective, we expect that STEPS UP will increase the percentage of military personnel with unmet PTSD- and depression-related health care needs who get timely, effective, and efficient PTSD and depression care. Our real-world primary care effectiveness emphasis will prevent the Institute of Medicine's so-called "15-year science-to-service gap." If successful, STEPS UP could roll out immediately, reinforcing and facilitating pathways to PTSD and depression recovery.

BODY:

Overall

Year 3 of this project covers the time period September 1, 2011 through August 31, 2012, during which a great deal of progress was made. As of August 31, 2012, five of our six installations were actively recruiting soldiers. Three of those five installations had soldiers eligible for the 3-month follow-up, and one installation had soldiers eligible for the 6-month follow-up.

Throughout Year 3, RTI engaged in a variety of administrative activities and tasks, including coordination with the larger STEPS UP team, as well as RTI-specific tasks. We have held weekly meetings with the full STEPS UP team and weekly calls with DHCC to discuss planning and to work out details of study logistics, such as coordination with RESPECT-Mil at installations, the securing of physical space on post, and facilitation of site IRB approvals. We have also held internal (RTI-only) weekly meetings to address the development of the RTI IRB protocol, instrumentation, website development and programming, and data collection logistics.

RTI submitted quarterly progress reports to CDMRP and in May 2012. Dr. Jordan Irvin requested that each of the three partnering institutions provide an updated jointly authored Statement of Work (SOW). All three institutions complied and submitted a revised SOW to Amber Stillrich on May 18, 2012.

IRB

In Year 3, the study received full IRB approval at all participating institutions as well as at all site-specific IRBs. RTI's initial IRB submission was approved internally in June 2011 (Year 2 of the project). During Year 3, there were six IRB amendments that were submitted to and approved by the RTI IRB. RTI submitted a continuing review application to the RTI IRB and received approval on May 2, 2012. On May 3, 2012, RTI sent a copy of that approval to Dr. Jordan Irvin and to HRPO. ***Table 1*** presents details of each amendment that was submitted to and approved by the RTI IRB during Year 3.

Table 1. 2011 IRB Amendments

2011 IRB Amendments (date approved by the RTI IRB)	**Highlight of Changes Requested and Approved**
24 August 2012	Request for use of incentives in the amounts of $40, $45, $50, and $55, respectively, for off-duty completion of our baseline, 3-, 6-, and 12-month follow-up assessments. Incentives will be in an electronic form; participants will receive electronic credits for use at Amazon.com.
13 June 2012	Deletion of exclusion criterion re: Medical Evaluation Board Sending of auto reminder text messages and/or mailings to those who have consented to this means of contact Review of prompting text for site coordinators to use in contacting nonresponders Review of talking points for leaving follow up reminders on voicemail Use of emergency/alternate contact information after 20 days of nonresponse, or upon receipt that the email or phone number provided by the participant were inactive
2 May 2012 Continuing Review	Annual continuing review to extend the expiration of IRB approval (through 4/25/2013)
27 March 2012	Correction of a scoring error in previously submitted scoring and instrumentation documents Allowing participants to finish the screening section after indicating suicidal ideation/intent to a degree that warrants exclusion from the study (for patient safety purposes) Removal of deployment criterion for study inclusion
17 February 2012	Review of minor changes to the instrument Review of clinical emergency notification and escalation Revisions to Data Security process
10 November 2011	Review of final study marketing pamphlets Review of final cover letter for consent forms Review of final consent form Minor revisions to intro text for directions approved
30 September 2011	Review of minor text changes to instrument for clarity and usability purposes

Per IRB guidelines, RTI and all partnering institutions must report any adverse events to their respective IRBs. During Year 3, we had two such reportable events. The descriptions and actions required as a result are presented in ***Table 2***.

Table 2. Adverse Events Reported to the RTI IRB

Adverse Event	Description/Action
21 February 2012	Description/Action: Due to a programming error, an ineligible individual was allowed to be randomized by automated web system into our study on February 15, 2012. The individual reported suicidal ideation of a level more significant than what is allowed by our exclusion criteria. This error was discovered the afternoon of February 20, 2012. The programming error was fixed and tested to ensure proper functioning within 10 hours of discovery of the incident. A report was made by Kristine Rae Olmsted to our study colleagues at DHCC on Monday, February 20, at 2:45 PM. The study project director at DHCC, Dr. Mike Freed, initially contacted the individual's care provider within 48 hours of the individual's screening (i.e., when we learned of the level of his suicidal ideation on February 15), and the care provider agreed to follow up with the individual. No other reports have been made to date. (Please note that the participant in question was randomized by our automated system to the "treatment as usual" group. As such, the participant is receiving the care he/she would have received had he/she not been randomized as part of our study.) The participant was manually removed from the study, and their data were deleted permanently.
11 June 2012	Description/Action: Ft. Campbell on June 11, 2012: A soldier was consented for participation and, before beginning the eligibility instrument, began to show significant signs of distress: sweating, indicated feeling suicidal, and had a plan to end his life as well as the lives of his "NCOs." The soldier was escorted to clinic personnel and the ER by a member of his unit, per the clinic Standard Operating Procedure. The RTI site coordinator immediately notified the referring RESPECT-Mil nurse care facilitator of the incident. The study team confirmed that all appropriate clinical action was taken. The soldier had not completed the eligibility assessment for inclusion in the study. Based on the soldier's suicidal ideation, the individual was inelgible for study participation and has been excluded. We have reviewed the protocol and consent form and believe that no changes need to be made based on this event.

Web Instrument and Programming

The baseline questionnaire instrument was completed during 2011. Items included in the instrument were reviewed and evaluated by a methodologist for inconsistencies/errors, usability, burden, and other features. Web programming of the instrument and study participant randomization were also completed in 2011. RTI also began development and programming of the patient tracking system and reports. The study website was installed within RTI's Enhanced Security Network (ESN) to ensure security of study participant data.

In order to accommodate the changing needs of the study, the RTI Programming Team added additional members in March 2012.

During the past year, the study team determined that, in order to maximize participation rates, we needed to offer respondents the opportunity to complete follow-up instruments over the telephone, as administered by a trained interviewer. The development of this new element of the study has required comprehensive planning and requires IRB approval (forthcoming amendment submission). We plan to roll out this feature of the study in October 2012.

Secure Network

In early 2012, RTI finalized all screening and baseline instruments. During this same time, in preparation for study implementation at JBLM in February 2012, RTI moved all data systems to its ESN to ensure adequate protection of study-related data, including personal identifying information.

Emergency Notification

RTI, along with the larger study team at DHCC and RAND, developed and implemented a Clinical Emergency Reminder and Escalation Protocol to ensure patient safety. It was designed to provide assistance to respondents who screen positive (in either the screening or baseline portion of the instrument) for active, emergent suicidal ideation. When this occurs, the automated RTI web system sends alert text messages and e-mails to on-call clinicians, the site coordinator administering the intake, and several other key staff to alert them of the situation. The on-call clinician then contacts the site coordinator for a description of the respondent's condition and subsequently calls the respondent directly to assess their mental state. All participants who score sufficiently high on suicidal ideation to engage this emergency notification system are ineligible for the study. The system was tested thoroughly to ensure proper functioning, and continues to be tested regularly to ensure that proper notifications are being sent in a timely fashion.

Site Coordinators

Throughout 2011, RTI hired site coordinators at all six of our installations. Coordinators were trained in the study protocol and made familiar with procedures at their local site. We also hired an additional staff member responsible for telephone interviewing. The staffing at each site as of August 2012 is detailed in ***Table 3***.

Table 3. Site Coordinators: Staffing by Installation

Installation	Full-Time	Part-Time
JBLM	x	x
Ft. Bliss	x	x
Ft. Campbell	x	x
Ft. Carson	x	x
Ft. Stewart	x	*
Ft. Bragg	x	*
Phone Interviewer	--	x

*At present, part-time coordinators have not been hired at these installations. As we see an increase, or consistent upward trend, of available potential participants, RTI will hire and train qualified part-time coordinators to work in conjunction with the full time coordinator.

Data Collection

During Year 3, baseline and follow-up instruments were finalized, programmed, tested, and implemented via our secure web portal. During this same time period, five of six installations were actively recruiting and enrolling participants, and one was holding regular meetings in preparation for starting data collection. Data collection details for these sites are presented in ***Table 4***.

Table 4. Data Collection in Year 3

Installation	Date Enrollment Began	Total Randomized through 31 Aug 2012	Total Eligible for 3-Month Follow-Up	Total Completed 3-Month Follow-Up Through 31 Aug 2012
JBLM	6 Feb 2012	105	66	44 (66.7%)
Ft. Bliss	2 Apr 2012	41	17	8 (47.1%)
Ft. Campbell	23 Apr 2012	21	2	1 (50.0%)
Ft. Carson	17 Aug 2012	0	0	0 (n/a)
Ft. Stewart	30 Aug 2012	0	0	0 (n/a)
Ft. Bragg	IRB approval pending	0	0	0 (n/a)
TOTAL		167	85	53 (62.4%)

Reminder Schedule

RTI called on team members to devise a reminder schedule geared toward securing continued study participation. We anticipate implementation of this plan subsequent to RTI IRB approval (anticipated in September 2012). These timeframes are for 3-month and 6-month follow-up assessments. A soldier's window for a follow-up begins 30 days before he/she hits the mark and continues for 2 months after the mark. Thus, a solider enters the 3-month window after 2 months (60 days) and remains in the window for 90 days, which is 2 months (60 days) after the 3-month mark. That means soldiers are within the data collection window for 90 days: 30 days before the 3-month mark and 60 days after.

Qualitative Study

In late May 2012, RTI began submitting selected participant contact information to RAND for purposes of facilitating their qualitative portion of the study. Participant contact information is sent both encrypted and password-protected. RTI will continue to send this information to RAND every 2 weeks until their recruitment goal for the qualitative study is met.

Incentives

The larger study team discussed extensively the benefits of being able to offer incentives to participants who provide study-related data during off-duty hours. After many discussions with experts in data collection methodologies with military populations, all three partnering institutions advocated for an incentive structure covering baseline, 3-month, 6-month, and 12-month follow-ups. Approval from Walter Reed for these incentives is pending.

Year 3 Challenges

RTI has not received project funds beyond those allocated in Year 2. Although we have worked to conserve where possible (i.e., we have contained expenses for 3 years to the Years 1 and 2 funds), we expect to deplete Year 2 approved funds in November 2012. In September 2012, RTI's contract office will submit an e-mail to USAMRAA requesting release of additional funding. Our current funds (total of Year 1 and Year 2) will cover RTI's project related costs through approximately October 2012. Once project funds are exhausted, RTI will be required to stop work on the project, potentially undermining the tremendous progress described in this report.

As the study has progressed, we have learned that ongoing fine tuning to our web assessment instruments has been necessary. In addition, due to these complexities and the need for detailed participant information by site coordinators, it became clear that we needed to develop a complex control system. This system is currently under development. We plan to have it completed and active in mid-October 2012.

Efforts to increase follow-up participation rates and other tasks have taken more time than was assumed in our original proposal. As a result, one of our concerns is that these activities will have cost implications as the study progresses. We will continue to monitor our costs closely and look for ways to improve efficiency.

KEY RESEARCH ACCOMPLISHMENTS:

The key research accomplishments for Year 3 are as follows:

- the completion and programming of all study instruments (baseline and follow-up);
- the hiring, training, and preparation of staff at installations;
- ongoing refinement of protocol issues (as evidenced by six IRB amendments); and
- the initiation of data collection at five of six installations.

REPORTABLE OUTCOMES:

There are no reportable outcomes to date, as we are still collecting data.

CONCLUSION:

There are no conclusions to report at this time, as we are still undergoing regulatory review.

REFERENCES:

None